LABEL IN PART: (Ctn.) "Visan Assurance Food Supplement Contents 60 Red Vitamin Capsules 180 Green Mineral Tablets 1 month supply for 1-adult or teenager."

CHARGE: 502(f)(1)—while held for sale, the labeling of the articles failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which they were intended, namely, arthritis, eczema, hardening of the arteries, hay fever, nervous stomach, high blood pressure, sinus diseases, migraine headache, heart disease, run-down condition, constipation, stiff neck, swollen knees and fingers, asthma, coughs, nervous conditions, goiter, colitis, sugar diabetes, and sore and bleeding hands, which were the diseases, symptoms, and conditions for which said article was held out to the persons present at the aforesaid sales talk.

PLEA: Not guilty.

DISPOSITION: On 1–11–61, the defendant was found guilty after a trial by the court without a jury, and, on 3–7–61, was fined $250 and placed on probation for 2 years.

6551. Tri-Wonda Treatment (Tri-Wonda Nos. 1, 2, and 3). (Inj. No. 270.)

COMPLAINT FOR INJUNCTION FILED: 3–3–54, S. Dist. Miss., against Lela S. Wier, t/a Wonda Products Co., Jackson, Miss.

NATURE OF BUSINESS: The defendant was engaged in distributing and selling the drug "Tri-Wonda." This drug consisted of three component parts which were packed in separate containers. One bottle of "Tri-Wonda No. 1," two cans of "Tri-Wonda No. 2," and three bottles of "Tri-Wonda No. 3" constituted a "*Tri-Wonda Treatment.*" "Tri-Wonda No. 1" was a combination of dilute hydrochloric and dilute nitric acid with traces of tartaric and acetic acids; "Tri-Wonda No. 2" was a mild laxative containing cream of tartar, senna, sulfur and phenolphthalein; and "Tri-Wonda No. 3" consisted of a 44 percent alcohol solution of fluid extract of Jamaica dogwood, thiamine hydrochloride, and wild cherry flavoring. The drug was sold by the defendant for use by sufferers of arthritis, rheumatism, and bursitis.

CHARGE: The complaint alleged that the drug "Tri-Wonda" was introduced into interstate commerce, and held for sale after shipment in interstate commerce, by the defendant, with labeling containing false and misleading representations that the drug was effective in the treatment of muscular aches, pains, soreness, stiffness, swellings, bursitis, rheumatism, and arthritis.

The complaint alleged further that the defendant was engaged in distributing, selling, and introducing and delivering for introduction into interstate commerce, the drug "Tri-Wonda" which was misbranded within the meaning of 502(a) of the Act in that its labeling contained false and misleading statements.

The complaint alleged further that the defendant was associating and causing to be associated with the drug "Tri-Wonda," after the drug had been shipped in interstate commerce and while it was held for sale, labeling containing false and misleading statements concerning the drug's therapeutic efficacy; which acts of the defendant resulted in "Tri-Wonda" being misbranded within the meaning of 502(a) of the Act.

It was alleged further that, if the defendant were restrained from using the labeling complained of, she would, unless enjoined, continue to merchandise the "*Tri-Wonda Treatment*" without the use of such labeling. In that case, the "*Tri-Wonda Treatment*" would be misbranded within the meaning of 502(f)(1) of the Act, if it were intended for use in the treatment of muscular

aches, pains, soreness, stiffness, swellings, bursitis, rheumatism, and arthritis since its labeling would not bear adequate directions for use in the treatment of all of the diseases and conditions for which the article was intended.

DISPOSITION: On 3–15–54, the defendant filed an answer to the complaint, denying that "Tri-Wonda" was misbranded and denying that she had represented to prospective purchasers in the labeling of the drugs that "Tri-Wonda" had any effectiveness beyond the capacity to give relief from certain symptoms and distress accompanying arthritis and rheumatism. The defendant's answer further stated that the drug would provide some or all such relief in a substantial proportion of cases.

On 8–5–54, upon agreement of counsel in open court, the court ordered the consolidation for trial of this injunction action with a seizure action in which 11 100-lb. drums and 1,526 4-oz. cans of "Tri-Wonda No. 2," and 7,306 2-oz. bottles of "Tri-Wonda Nos. 1 and 3" had been seized (see D.D.N.J. No. 6568). Thereafter, both sides filed written interrogatories and the Government filed two series of requests for admissions. Trial on the issues of both the libel and the injunction began on 9–26–55. There were recesses, and the testimony was completed on 6–21–56, after nearly 7 weeks of actual trial. The case was taken under advisement by the court.

On 10–22–58, the court confirmed the condemnation of the articles seized in the libel action, but found that the Government was entitled to only partial relief in the injunction action. The court made the following findings of fact and conclusions of law:

MIZE, *District Judge:*

FINDINGS OF FACT

"1. The defendant, Lela S. Wier, trading as the Wonda Products Co., Jackson, Mississippi, at the time of filing of this suit and for sometime past, has been introducing and causing to be introduced into interstate commerce at Jackson, Mississippi, a combination of three drug products called the 'Tri-Wonda Treatment,' intended for use in the treatment of arthritis, rheumatism and bursitis.

"2. The 'Tri-Wonda Treatment' is recommended in its labeling for the treatment of arthritis, rheumatism, bursitis, neuritis, neuralgia, sciatica, and for muscular aches, pains, soreness, stiffness, swelling and limitation of motion which accompany these diseases (Gov. Exs. 4, 15, 26, 27); spurs in the heel, and sciatic cramps and pains (Gov. Ex. 26).

"3. The 'Tri-Wonda Treatment' is composed of Tri-Wonda No. 1, Tri-Wonda No. 2, and Tri-Wonda No. 3.

"4. Tri-Wonda No. 1 is a combination of dilute hydrochloric and dilute nitric acids with traces of tartaric and acetic acids. Dosage recommendation is six drops in four ounces of water after meals. (Gov. Ex. 4.)

"5. Tri-Wonda No. 2 is a combination of tartar, senna, sulphur and phenolphthalein, a mild laxative to be taken at bed time, one teaspoonful mixed in ½ glass of water. (Gov. Ex. 4.)

"6. Tri-Wonda No. 3 consists of fluid extract of Jamaica dogwood, thiamine hydrochloride, and wild cherry flavoring dissolved in 44% alcohol. Twenty-five drops in two ounces of water are to be taken ½ hour before meals. (Gov. Ex. 4.)

"7. About 1900, Rev. H. A. Hall, a minister of the gospel, had a formula for a medicine which he labeled 'Hall's Muneac,' 'Hall's Laxative Powder,' and 'Hall's Compound.'

"8. 'Hall's Muneac' was recommended for a long list of diseases, including Bright's disease, diabetes, neuralgia, hookworm, high blood pressure, indigestion, gallstones, ulcerated stomach, dengue fever, common cold, influenza, tonsillitis, scarlet fever, as well as arthritis and rheumatism. (Gov. Ex. 88.)

"9. In 1938, Rev. H. A. Hall and his wife, Mrs. Hallie B. Hall, stipulated with the U.S. Post Office Department to discontinue using the mails for

marketing Hall's remedies. (Gov. Ex. 93.) Thereafter, these drugs were compounded and sold only in Tampa, Florida, at the home of the Halls.

"10. In 1950, the defendant, Mrs. Lela S. Wier, who had rheumatoid arthritis, first took the Hall products and she attributed improvement in her condition to the Hall drugs.

"11. Three months thereafter, she obtained the formula for these three Hall products and, after making some changes in it, began marketing them for use in the treatment of arthritis and rheumatism under the name of 'Tri-Wonda.'

"12. The formulas of the Tri-Wonda products are substantially the same as the Hall medications except that the strength of the acids and the dosage of Tri-Wonda No. 1 are reduced, and thiamin hydrochloride has been added to Tri-Wonda No. 3.

"13. In 1951, the defendant was told by physicians of the Food and Drug Administration in Washington, D.C., that Tri-Wonda was worthless in treating arthritis. In 1952, she was advised by officials of the Administration that the labeling of Tri-Wonda which promoted it as an arthritic remedy was false and misleading.

"14. In 1953, in cause No. 1929, the United States seized a large stock of the Tri-Wonda drugs, 'Special Bulletin,' and 'Dear Friend' letters (Gov. Ex. 40), charging that the bulletin and letters were labeling and falsely represented these drugs to be an adequate and effective treatment for arthritis, rheumatism and bursitis.

"15. In 1954, the United States filed its complaint in cause No. 2106, for injunction in this proceeding charging that the labeling of the Tri-Wonda drugs suggested and represented them to be effective in the treatment of muscular aches, pains, soreness, stiffness, swellings, bursitis, rheumatism and arthritis, which labeling was false and misleading since these drugs were not effective in the treatment of these conditions. The injunction proceeding and the seizure were tried concurrently. In March 1954, defendant answered the complaint, in which answer the defendant, Lela S. Wier, specifically denied all of the allegations that the labeling of the Tri-Wonda medicines has been, is now, or will be misbranded in violation of the various statutes cited, and specifically denied that the representations in the labeling of such products are false and misleading. The answer alleges that, in carrying on her business, the defendant has truthfully represented in the labeling and advertising of her drug products to prospective purchasers thereof that the three drug products designated 'Tri-Wonda No. 1,' 'Tri-Wonda No. 2' and 'Tri-Wonda No. 3,' when taken in accordance with the directions, have the capacity to give relief from certain symptoms and distress accompanying bursitis, rheumatism and arthritis, including: pain, soreness, the swelling of tissues around joints; the loss of freedom of motion resulting from pain, soreness and the swelling of tissues around the joints; the loss of general well being; constipation; and the deficiency of vitamin B_1 associated with arthritis and rheumatism; and that said drugs, when used in accordance with the directions by persons so suffering, have provided, do provide, and will provide some or all of the foregoing relief in a substantial proportion of cases.

"16. Defendant has been, and was at the time of filing the complaint herein, introducing the 'Tri-Wonda treatment' into interstate commerce, accompanied by letters, pamphlets, and circulars which suggest and recommend that these drugs are effective in the relief of muscular aches, pains, soreness, swelling, arthritis, rheumatism, bursitis and sciatica.

"17. Defendant has advertised the 'Tri-Wonda treatment' in over 5,000 newspapers under the title 'ARTHRITIS?', stating that she has been restored to active life and received wonderful relief. Readers were invited to write for details. (Gov. Ex. 5.)

"18. In response to inquiries from prospective customers various types of promotional material have been sent out, including 'Special Bulletin' (Gov. Exs. 6, 7, 8, 45), 'Dear Friend' letters (Gov. Exs. 9, 14, 16, 44) prior to March 1953, and since that time other form letters of various types (Gov. Exs. 10, 11, 12, 13), testimonial letters (Gov. Ex. 15), personal letters containing many stock paragraphs used to answer various inquiries (Gov. Exs. 18, 19, 20, 21, 22, 23, 24, 26, 36, 42, 81), leaflets containing customers' pictures and testimonials (Gov. Exs. 26, 27), and leaflets entitled 'Attention Arthritics' (Gov. Ex. 72).

"19. Some of the letters, leaflets and testimonials used in promoting and marketing the 'Tri-Wonda treatment,' suggest and represent the three drugs to be an adequate and effective treatment for muscular aches, pains, soreness, stiffness of the joints, swelling of tissues around the joints, loss of freedom of motion of the joints, and for arthritis, rheumatism and bursitis.

"20. A substantial number of persons who read those letters, testimonials and leaflets receive the impression that the 'Tri-Wonda treatment' is a cure for all forms of arthritis and rheumatism. (Dr. Mosel, Gov. Exs. 66, 67, 68, 69, 70.)

"21. There are many types of rheumatic diseases. The cause of some are known; that of others, unknown. Accepted medical treatment for the various forms of rheumatic diseases varies widely.

"22. It is a characteristic of many rheumatic diseases that they subside spontaneously for periods varying from a few days to several years; some regressions are permanent. On these occasions the patient is free of pain, swelling, soreness, and limitation of motion. Relapses are frequent with the return of the disease and resumption of the symptoms stated. These remissions and relapses are generally recurrent over periods of years.

"23. Specific medications and treatments can cure some types of rheumatic diseases including gouty, tubercular and gonococcic arthritis, and arthritis due to other specific types of infection. Delay in obtaining proper treatment for these types of arthritis may result in destruction of the affected joints and permanent crippling.

"24. At the present time there is no known cure for rheumatoid arthritis and osteoarthritis, although extensive research work is being conducted in many hospitals, clinics and laboratories. Approximately 80% of rheumatic patients suffer from these two types of arthritis.

"25. The medical profession use the salicylates, gold salts, cortisone, hydrocortisone, ACTH, and other steroid type drugs in the treatment of rheumatoid arthritis and osteoarthritis. Physiotherapy and surgery, including immobilization of joints, are sometimes resorted to in severe cases.

"26. The Government contends that the defendant has suggested and represented in the labeling that the Tri-Wonda medicines are effective in the treatment of muscular aches, pains, soreness, stiffness, swellings, bursitis, rheumatism and arthritis, that these statements are false and misleading in that the Tri-Wonda medicines are not effective in the treatment of such conditions and diseases.

"27. The defendant contends that she has truthfully represented, in the labeling of her products to prospective purchasers, that the Tri-Wonda medicines, when taken in accordance with the directions, have the capacity to give relief from certain symptoms and distress accompanying arthritis, rheumatism and bursitis, including: pain, soreness; the swelling of tissues around joints; the loss of freedom of motion resulting from pain, soreness, and the swelling of tissues around joints; the loss of general well being; constipation; and the deficiency of vitamin B_1 associated with arthritis, rheumatism and bursitis; and that said drugs, when used in accordance with the directions by persons so suffering, have provided, do provide, and will provide some or all of the foregoing relief in a substantial proportion of cases, and that she has, in good faith, without intent to defraud, continuously made a sincere, honest effort to avoid any false or misleading representation in the labeling of the Tri-Wonda medicines, directly or by implication; that it has never been and is not now her desire or intention to make any false or misleading representation of these products; that it is her intention at all times to comply with the law, particularly the provisions of the Federal Food, Drug and Cosmetic Act. That in the labeling of her products, the defendant stands ready to correct and offers to correct the labeling by removal of such representations.

"28. The court finds that the 'Special Bulletin' (Gov. Exs. 6, 7, 8) and the 'Dear Friend' letter (Gov. Ex. 9) contain statements representing and suggesting by implication that the Tri-Wonda medicines are a cure or remedy for any and all forms of rheumatism; that the evidence establishes that the Tri-Wonda medicines do not constitute a cure or remedy for any and all forms of rheumatism; and such representation is, therefore, false. However, this representation was made in good faith, without intent to defraud any purchaser or prospective purchaser. I further find that the use and distribution

of the printed leaflet entitled 'Special Bulletin,' and the 'Dear Friend' letter were abandoned and discontinued by the defendant sometime in 1953 and before the complaint for injunction was filed, and have not been used or distributed by the defendant since that date to the present time.

"29. The court finds that the Government has failed to meet the burden of proof and establish that the statements in some of the labeling used and distributed by the defendant, Lela S. Wier, the correspondence and the printed leaflets, are false and misleading, and has failed to prove that the Tri-Wonda medicines, when taken according to directions are not beneficial in a substantial number of cases in the treatment of some of the symptoms of arthritis, rheumatism and bursitis, including: pain, soreness, the swelling of tissues around the joints; the loss of freedom of motion resulting from pain, soreness and the swelling of tissues around the joints; the loss of general well being; constipation; and the deficiency of vitamin B_1 associated with arthritis, rheumatism and bursitis."

CONCLUSIONS OF LAW

"1. The Court has jurisdiction of the parties and the subject matter of this proceeding under the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 332(a).

"2. The circulars, leaflets, testimonials, form letters, and letters consisting of stock paragraphs which have been and are now used in the sale and distribution of the 'Tri-Wonda treatment' constitute 'labeling' within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321(m).

"3. That some of the labeling of the 'Tri-Wonda treatment' represents and suggests that the drugs are effective in the treatment of arthritis, rheumatism, bursitis, sciatica and neuritis, and the muscular aches, pains, soreness, stiffness, swelling and loss of freedom of motion of joints which accompany said diseases, which labeling is false and misleading within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 352(a), in that the 'Tri-Wonda treatment' is not effective in the treatment of all these diseases and conditions.

"4. The 'Special Bulletin' and the 'Dear Friend' letter represent and suggest by implication that the Tri-Wonda medicines are a cure or remedy for any and all forms of rheumatism and such representation in the labeling is false and misleading within the meaning of U.S.C. Title 21, Section 352(a).

"5. The defendant, Lela S. Wier, an individual trading as the Wonda Products Company, may continue to distribute and sell the Tri-Wonda medicines in interstate commerce provided the labeling thereof is not false and misleading and is limited to representations that the Tri-Wonda medicines, when taken according to directions, are beneficial in a substantial number of cases in the treatment of the following symptoms of rheumatoid arthritis, rheumatism and bursitis: pain, soreness, the swelling of tissues around joints; the loss of freedom of motion resulting from pain, soreness, and the swelling of tissues around joints; the loss of general well being; constipation; and the deficiency of vitamin B_1, associated with arthritis, rheumatism and bursitis.

"6. The Government is entitled to a permanent injunction restraining the interstate distribution of Tri-Wonda No. 1, No. 2 and No. 3 labeled in any manner which represents or suggests them as a treatment for any rheumatic disease except as set out and limited in the foregoing opinion and conclusions of law.

"7. The Government is entitled to a permanent injunction restraining the interstate distribution of Tri-Wonda No. 1, No. 2 and No. 3 unless the labeling of each bears adequate directions for use in the treatment of all diseases, symptoms or conditions for which these drugs are intended. 21 U.S.C. 352(f)(1).

"Order will be settled in accord herewith."

A decree of permanent injunction which granted the Government partial relief was filed on 1–16–59. Both Government and the defendant filed notices of appeal to the United States Court of Appeals for the Fifth Circuit, which heard the appeals on 4–26–60.

On 8–8–60, the court of appeals handed down the following opinion reversing the judgment of the district court (281 F. 2d 850):

TUTTLE, *Circuit Judge:* "This is an appeal by the United States from an order granting an injunction against some, but not all, of the claims of the appellee used in the interstate sale of her patent medicines, Tri-Wonda No. 1, Tri-Wonda No. 2, and Tri-Wonda No. 3.[1]

"These medicines were sold by appellee for use by sufferers of arthritis, rheumatism and bursitis. The Government's appeal results from the fact that the decree of the trial court enjoined the defendant from distributing the products in interstate commerce when misbranded by representing that they or any similar drug are 'a cure or adequate treatment for any form of arthritis or rheumatism' but which decree expressly stated that 'she could continue to introduce the drug into interstate commerce provided the labeling thereof was not false and misleading, permitting her to represent that the Tri-Wonda medicines, when taken according to directions, are beneficial in a substantial number of cases in the relief of some symptoms of rheumatoid arthritis, rheumatism and bursitis, such as pain, soreness, the swelling of tissues around the joints; the loss of freedom of motion resulting from pain and soreness accompanying rheumatoid arthritis; the loss of general well being; constipation; and the deficiency of vitamin B–1 associated with arthritis, rheumatism and bursitis . . . .'

"The United States complained of the permissive part of the order and the failure of the court to enjoin the representation that 'the drugs were beneficial in a substantial number of cases in the relief of some symptoms of rheumatoid arthritis, rheumatism and bursitis such as pain, soreness, the swelling of tissues around the joints, and the loss of freedom of motion resulting from pain and soreness accompanying rheumatoid arthritis' on two grounds: (1) the acts enjoined by the court could not be distinguished from the acts permitted and thus 'the decree contains inconsistencies and ambiguities which make it unenforceable,' and (2) such representations as are permitted by the Court are wholly unjustified by the evidence of record.

"The trial court made explicit findings of fact, which included the following:

> . . . that the evidence establishes that the Tri-Wonda medicines do not constitute a cure or remedy for any and all forms of rheumatism; and such representation is, therefore, false. . . .

Finding No. 29, to which the Government directs its attack, is as follows:

> 29. The court finds that the Government has failed to meet the burden of proof and establish that the statements in some of the labeling used and distributed by the defendant, Lela S. Wier, the correspondence and the printed leaflets, are false and misleading, and has failed to prove that the Tri-Wonda medicines, when taken according to directions are not beneficial in a substantial number of cases in the treatment of some of the symptoms of arthritis, rheumatism and bursitis, including: pain, soreness, the swelling of tissues around the joints; the loss of freedom of motion resulting from pain, soreness and the swelling of tissues around the joints; and loss of general well being; constipation; and the deficiency of vitamin B_1 associated with arthritis, rheumatism and bursitis.

"Among the three questions presented by appellee in her brief is the following: 'Is Finding of Fact No. 29 in the decision below contrary to the overwhelming evidence, so that it is completely erroneous?' In our view of the case this question must be answered in the affirmative, thus making unnecessary an answer to the first contention of the Government.

"In approaching the problem as to the duty and power of the appellate court when called upon to review a finding of fact by the trial court, sitting without a jury, we start with the basic rule:

[1] Tri-Wonda No. 1 is a combination of dilute hydrochloric and dilute nitric acids with traces of tartaric and acetic acids. Tri-Wonda No. 2, which is a combination of cream of tartar, senna, sulphur, and phenolphthalein, is a mild laxative. Tri-Wonda No. 3 consists of fluid extract of Jamaica dogwood, thiamin hydrochloride (vitamin B_1) and wild cherry flavoring dissolved in 44% alcohol.

Rule 52. FINDINGS BY THE COURT.

(a) Effect. In all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon and direct the entry of the appropriate judgment; and in granting or refusing interlocutory injunctions the court shall similarly set forth the findings of fact and conclusions of law which constitute the grounds of its action. Requests for findings are not necessary for purposes of review. Findings of fact shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses. . . .

Although the trial court's finding here was stated in terms of a failure of the Government 'to meet the burden of proof and establish that the statements . . . are false and misleading,' we consider this simply as a finding against the Government on the evidence.

"It will at once appear to anyone dealing with an effort to prove that certain chemicals do or do not have a therapeutic effect on the human body, that the investigator, here the trial court, must do more than simply pass upon the credibility of the witnesses in ascertaining whether there is any evidence substantial enough to support the finding pro or con. For instance, we have held in *United States* v. *Hoxsey Cancer Clinic*, 5 Cir., 198 F. 2d 273, that the testimony of a layman, either that he is suffering from cancer or that he has been cured of cancer, however honestly given and however firmly believed, does not rise to the dignity of substantial evidence. It follows that the same is true as to any disease whose presence or cure can be ascertained only by persons trained in medical science and by the use of scientific aids or surgery.

"We think that what has been said as to the diagnosis of disease by a layman, even though he be a sufferer, applies with equal force to an opinion given by a sufferer that his relief from pain or relief from other symptoms of a disease is the result of the taking of specific medicines. Certainly a statement by a patient whose diet is not otherwise controlled or brought into the inquiry, who may be taking other medicines at the same time, and particularly in a disease which has a high rate of remissions, that his pain, swelling or limitation of movement has been helped by Tri-Wonda, cannot amount to substantial evidence, even though it be technically admissible.

"Dealing with just such an appeal by the Government from a finding by the trial court that it 'had failed to carry the burden of establishing the truth of the allegations of its complaint' this Court, in the Hoxsey case clearly established the law which must guide us here.

"There, as here, highly qualified experts in the field of medicine involved (there, cancer, here arthritis) testified uniformly that the disease could not be diagnosed without the use of scientific aids not used by the witnesses for the appellee in either case; that the cause of the disease was unknown and the known treatment of it of very doubtful efficacy at best; that great amounts of research had been carried on to broaden the field of knowledge of the medical profession as to cause and cure. There, as here, there was testimony on behalf of the Government resulting from clinical studies made by those medical men who had specialized in the field, which tests were made with controls and with care to make most likely the possibility of an objective ascertainment of the truth and there was also testimony for the respondent from others not specialists in the field based on clinical tests made in disregard of the major recognized safeguards to an objective test. There, as here, pharmacologists, those skilled in the knowledge of the effect of chemicals on the human organs and functions, testified to the worthlessness of the drug in question when used as directed for the stated purposes. There, as here, there were doctors and patients who nevertheless testified, obviously without the necessary foundation for basing an opinion, that the medicine did offer relief or cure.

"Notwithstanding the testimony which, in another type of case, it might be said would create a conflict, the Court, speaking through Judge Russell, said:

Thus, even if it be assumed, arguendo, that there is some measure of conflict in the evidence relating to the falsity of the specific representa-

> tions referred to above, still, it is clear that a finding that such representations are true is not supported by substantial evidence.

And, further:

> We think this so-denominated conflicting evidence, wholly insufficient to cast such doubt upon the testimony adduced in behalf of the Government as to authorize the trial court to find that the Government had failed to carry the burden of establishing the truth of the allegations of its complaint. 198 F. 2d 273, 280, 281.

"In this case the evidence on behalf of the United States was impressive. Specialists in the field of arthritic diseases, active in arthritic research and members of the learned societies dealing with this medical specialty, one of whom testified that he had treated approximately 40,000 arthritic patients, one orthopedic surgeon and two research specialists, testified without equivocation that the ingredients of these three patent medicines in the quantities recommended for treatment were without therapeutic value either in the treatment of, or alleviation of the symptoms of arthritis.

"In addition to the foregoing evidence three pharmacologists, experts in the field of drugs and their effect on the human system, also testified that the ingredients of Tri-Wonda were not recognized in any of the literature or teachings of the profession for the treatment of, or alleviation of the suffering, from arthritic diseases. They further gave their opinion that they had no value in relation to such disease.

"This evidence was countered, on behalf of the appellee, by five general practitioners, all of whom professed not to be specialists in the field, and all of whom made disparaging remarks concerning their own qualifications either to diagnose or treat the several types of arthritic diseases. Their testimony was almost without exception based upon tests [2] on patients sent to them by the appellee or on patients who had diagnosed their own condition and asked for treatment by obtaining a free course of medicine furnished by appellee.

"Appellant's brief is replete with specific excerpts of testimony relating to cases testified about by these general practitioners and their patients. Strikingly, appellee opens its brief with the following statement:

> Except for conclusions of the pleader as to the effect of evidence adduced, appellee believes the case is fairly stated in a part of the brief for appellant. Only the first page statement is accepted because the remainder of the statement by appellant is argument in advance.

Yet nowhere in the brief is a single statement of fact contained in the brief of the United States refuted or otherwise attacked by the appellee. We have carefully read the record references to the testimony of the 35 to 40 case histories which are carefully analyzed in the Government's brief and have found the conclusions drawn by the Government are completely accurate as to the effect of the testimony.

"In brief, it must be said that the evidence of not one of the five general practitioners rises to the quality necessary to constitute substantial evidence when considered in the light of the other evidence in the record. This is so because either the medical witnesses thoroughly disqualified themselves as having any skill in either diagnosis or treatment of the arthritic diseases or because their evidence as to the effectiveness of Tri-Wonda in alleviating pain, reducing swelling or improving mobility of joints was either merely a repetition of statements made to them by the patients, or because the record clearly discloses that there was no diagnosis of the existence of the disease either before or after the so-called treatment, or for both reasons. For instance one of the doctors testified: 'Everyone of these patients already had their own diagnosis made.' They all completely ignored the important differences in the cause and treatment normally accorded the different types of arthritis. They all testified they knew of no literature in the field that suggested the component parts of these medicines, taken singly or together, as being efficacious in the treatment of the disease.

[2] The circumstances under which these tests were given so far lacked the normal controls recognized even by these witnesses as proper to an objective ascertainment of the worth of a new drug that they cannot really be called "clinical tests."

"Even though otherwise not objectionable, the testimony of these witnesses amounted to nothing more than testimony from their individual personal experience. As to this kind of medical testimony Wigmore's comment is pertinent:

> To allow any physician to testify who claims to know solely by personal experience is to appropriate the witness stand to impostors. Medical science is a mass of transmitted and collated data from numerous quarters; the generalizations which are the result of one man's personal observation exclusively are the least acceptable of all. The law must recognize the methods of medical science. It cannot stultify itself by establishing, for judicial inquiries, a rule never considered necessary by the medical profession itself. It is enough for a physician, testifying to a medical fact, that he is by training and occupation a physician; whether his source of information for that particular fact is in part or entirely the hearsay of his fellow practitioners and investigators, is immaterial. Wigmore, Evidence, 3d ed., Vol. III, § 687.

"In addition to the testimony of the general practitioners above referred to, appellee introduced as a witness a Dr. Mary Gray, also lacking any special qualifications in the field of arthritic diseases, who merely undertook to interview a number of patients to whom she was sent by Mrs. Wier, the appellee. Her survey was, of course, based solely on the statements made to her by the customers who had already used the medicine before they were interviewed by her. A number of these persons who were reported by Dr. Gray to have stated that their condition had improved, testified as witnesses at the trial in which they repudiated such testimony.

"Finally, a Dr. Nellie Watts testified that she had searched the literature in the arthritic field and, based solely on this search she had made, she concluded that some of the chemicals in these medicines might act as a diuretic and, by lowering the water content of the body generally, reduce swelling of the joints. In view of the fact that two of the writers of the articles on which Dr. Watts principally relied, testified at the trial that the ingredients of these medicines in the quantities prescribed would not have the effect attributed to them, it appears that no reliance can be placed upon testimony based on their theory.

"The appellee strongly urges that there is a clear distinction between a contention that a medicine is recommended for the treatment of arthritis and a statement that a medicine will in some cases relieve the pain, swelling and limitation of movement associated with arthritis. We think we do not need to decide whether there is such distinction here as to make permissible the marketing of a product under the second representation which has been found not marketable under the first, because we think it clear beyond any question that the findings of the trial court that the Government had not carried its burden of proving that the Tri-Wonda medicines were not 'beneficial in a substantial number of cases in the relief of some symptoms of rheumatoid arthritis, rheumatism and bursitis, such as pain, soreness, the swelling of tissues around the joints, the loss of freedom of motion resulting from pain and soreness accompanying rheumatoid arthritis' was false and misleading is so 'against the great preponderance of the credible testimony that it does not reflect or represent the truth and right of the case.' *Sanders* v. *Leech, 5 Cir.*, 158 F. 2d 486, 487.

"We do not need to question the credibility of any of the witnesses. We assume that the trial court credited each of the appellee's witnesses with telling the truth. This does not, however, add any weight to testimony which, because of demonstrated lack of opportunity properly to base opinion, relegated such testimony to the class mentioned by this Court in the Hoxsey case as being contrary 'to all accepted scientific knowledge' and, therefore, not substantial.

"On the entire evidence we are left 'with the definite and firm conviction that a mistake has been committed.' *United States* v. *U.S. Gypsum Co.*, 333 U.S. 364, 395. The overwhelming weight of the evidence requires a conclusion that the representation that these medicines may relieve the pain or swelling or affect the limitation of movement accompanying rheumatoid arthritis is false and misleading.

"The trial court should, upon such evidence, have granted the injunction as prayed for and the court's failure to do so, as stated by us in the Hoxsey case, 'evidences an abuse of discretion.'

"REVERSED and REMANDED for further proceedings not inconsistent with this opinion."

CAMERON, *Circuit Judge*, Dissenting:

I.

"(a) This appeal by the United States is based upon 28 U.S.C.A. § 1291 investing this Court with jurisdiction of appeals from all final decisions of the district courts within the Fifth Circuit. The appellee filed and served a motion to dismiss the appeal upon the ground that the district court specifically retained jurisdiction of a portion of the claim sued on by appellant and that the judgment appealed from was not, therefore, a final judgment within the meaning of said statute. This Court ordered that the motion be argued along with submission of the appeal upon its merits, and that course was followed. In my opinion the motion of the appellee should be granted and the case should be remanded for such further hearing as the trial court may order, and the entry of a final judgment.

"It is necessary to understand that the court granted appellant an injunction exceedingly broad in its terms, as will appear from copy thereof set out in the margin.[3] The judgment did not grant appellee any injunction licensing her to introduce any drug at all into interstate commerce.

"The majority opinion states that the United States complained of the 'permissive part of the order,' which it quoted in paragraph 2 of the opinion. This statement was not made in the injunction portion of the judgment appealed from, but it was merely a recital in the preliminary paragraphs of the decree that the Government had failed to prove its claim with respect to whether the drugs were beneficial in a substantial number of cases in the relief of

---

[3] ". . . and it is further ordered, adjudged and decreed.

"2. That Lela S. Wier . . . be and they are hereby perpetually enjoined and restrained under the provisions of 21 U.S.C. 332(a) from directly or indirectly introducing or causing to be introduced or delivering or causing to be delivered for introduction into interstate commerce, an article of drug known as 'Tri-Wonda,' 'Tri-Wonda Treatment,' 'Tri-Wonda No. 1,' 'Tri-Wonda No. 2,' 'Tri-Wonda No. 3,' or any other name, consisting of the following ingredients: [giving in detail the constituent chemicals] . . . or any similar drug, the labeling of which is false or misleading in any particular, and more specifically any such drug which is accompanied by the leaflets introduced in evidence as exhibits, entitled 'You May Now Profit by the Experience of Others,' 'Attention Arthritics,' the letters entitled 'Special Bulletin,' 'Dear Friend,' 'Thank you for your letter of recent date,' 'I am glad to tell you about my experience,' and testimonial letters from users of Tri-Wonda, or any other written, printed, or graphic matter, which represents or suggests, directly or indirectly, that the drugs, or either of them, or any similar drug, is a cure or adequate treatment for any form of arthritis or rheumatism, or that they are beneficial, or give relief or have any value for all forms of arthritis and rheumatism, or that they are beneficial, effective, or have any value in the cure, mitigation, relief, or treatment of muscular aches, pains, soreness, stiffness, and swellings which accompany gouty, tubercular, gonococcic arthritis or arthritis due to specific types of infection, sciatica or neuritis; and it is further—

"3. Ordered, adjudged and decreed that the defendant, Lela S. Wier, . . . be and they are hereby perpetually enjoined and restrained from directly or indirectly doing or causing to be done any of the following acts with respect to the aforesaid drug while held for sale after shipment in interstate commerce:

"(a) The use in the sale of the drug of any of the written, printed or graphic matter referred to in paragraph 2, or of any other written, printed, or graphic matter containing any of the claims or representations specified in paragraph 2.

"(b) Representing, in any manner, that the drug is useful in the prevention, treatment, mitigation, or cure of any disease, condition, or symptom, that is not stated and/or enumerated in the labeling thereof together with precise directions for effective and safe use in each such disease, symptom, or condition; and it is further—

"4. Ordered, adjudged and decreed that the defendant, Lela S. Wier, . . . be and they are hereby perpetually enjoined and restrained from directly or indirectly introducing or causing to be introduced or delivering or causing to be delivered for introduction into interstate commerce the aforesaid drug with labeling that does not include a statement and enumeration of all diseases, conditions and symptoms, for which the article is intended to be used, together with precise directions for effective and safe use in each such disease, condition, or sympton; . . . [Emphasis added.]

some symptoms of the diseases such as pain, soreness, swelling, constipation, etc.[4]

"Patently, in order to leave its finding No. 29 and its recital in the introductory portion of the order appealed from open for further testimony or action by either party, the court added, as the last paragraph (except that dealing with costs) of the injunctive order, the following:

> 6. Ordered, adjudged and decreed that the jurisdiction of this Court is retained for the purpose of enforcing this decree and for the purpose of granting such additional relief as may hereafter appear necessary or appropriate . . .

"This plain retention of jurisdiction by the court below, under the undisputed circumstances as set forth above, in my opinion, rendered the judgment unappealable. The general rule in such matters was thus stated by the Supreme Court in *Covington* v. *Covington First National Bank*, 1902, 185 U.S. 270 (syllabus):

> Matters within the pleadings in this case having been left undetermined by the court below, and the cause having been detained for the purpose of thereafter passing upon them, and for the entry of a further decree, the decree entered below was not final, and this Court is without jurisdiction to pass upon it.[5]

It is provided in Rule 54(c) F.R.C.P.:

> . . . every final judgment shall grant the relief to which the party in whose favor it is rendered is entitled . . .

Under this Rule and the language of § 1291 the case before us comes, in my opinion, precisely under our holdings in *King* v. *California*, *supra*.

(b) If appellant thought, as it now claims that the judgment of the court below was 'Ambiguous and Inconsistent' as it argues in the first point in its brief, it had the right under Rule 59(e) to serve 'A motion to alter or amend the judgment not later than ten days after entry of the judgment.' Having failed so to do, it cannot, in my opinion, attempt to put the court in error by a point raised in the first time on appeal. The judgment showed clearly on its face that it was not final and that jurisdiction was retained for further hearing on the very matter upon which appellant lays most stress. The right to appeal to this Court is statutory and the right does not, in my opinion, for the reasons set forth, exist.

II.

"I am unable to follow the majority in holding that the district judge was clearly erroneous in his holding that the drugs in question had been shown to be beneficial in the treatment of certain symptoms in a substantial number of people. This case was at issue in the early part of March 1954, and was tried at intervals when the district court could get around to it until its opinion was rendered October 22, 1958. The judgment appealed from was not entered until January 16, 1959. In nearly all instances the court heard the vast number of witnesses testify personally. The record is in nineteen volumes and contains 3,759 pages. Unless an appellate court is to read all of those pages, I do not see how it is in position to adjudge the findings of fact of the court, which heard all of the witnesses testify and all of the arguments and objections, were clearly erroneous under Rule 52 F.R.C.P.

"I do not think we should be overawed by the asserted high standing of some of the Government's witnesses. The United States is a rich litigant and is able to produce the best in the way of expert testimony. Without

---

[4] This recital portion of the decree contained this further statement: "The Court did not adjudicate that the drug was beneficial, but only that the Government had failed to prove that it was not beneficial in the above respects . . ."

[5] To the same effect see City of Paducah 1. East Tennessee Telephone Co., 1913, 229 U.S. 476; 6 Moore's Federal Practice, 2d Ed. pp. 120 et seq.; King v. The California Co. et al., 5 Cir., 1955, 224 F. 2d 193, same case, 1956, 236 F. 2d 413. And cf. New Amsterdam Casualty Co. v. B. L. Jones & Co., 5 Cir., 1958, 254 F. 2d 917; Richards et al. v. Smith et al., 5 Cir., 1960, . . . F. 2d . . . .

reflection upon this character of testimony it can be said that all lawyers of experience know that experts generally stick pretty close to the line of the testimony of the litigant which employs them.

"Appellee's experts were general practitioners who were constantly called upon to treat people suffering from arthritis, rheumatism and the other maladies which the accused literature dealt with. Such doctors acquire necessarily a good working knowledge of palliatives which will give a measure of relief, even though probably temporary, to the symptoms attending those ailments. Certainly the Government does not desire that the average doctor be encouraged to sit idly by and permit people to suffer day after day because those in higher places have not discovered a cure for these common maladies. The trier of facts in this case had the right to consider their testimony and to give it such weight as he thought it deserved.

"The average man also has a pretty good idea of the symptoms which go with rheumatism and arthritis. Sufferers from them are legion and nobody, it seems to me, would deny that a witness may testify to the symptoms he has as the result of a malady diagnosed by a medical man as rheumatism or arthritis, and to testify that certain drugs have given him relief. That is all that the appellee's witnesses attempted to do, and that is the sole question involved in this appeal, that is, relief of certain symptoms to a substantial number of people suffering from the maladies listed in the judge's findings.

"The majority opinion does not attempt to analyze the testimony of the laymen who stated unequivocally that they were sufferers from these maladies and that their sufferings were alleviated by the use of the drugs in question. As a matter of interest, it will be found that twenty-two laymen did so testify. Excerpts from their testimony are set forth in the margin.[6] Even

---

[6] Mrs. George Bosarge:

Q. "Referring to your lower spine, were you suffering pain there?"
A. "Terribly." . . .
Q. "Did you take those three medicines home with you?"
A. "I did."
Q. "Did you take them as prescribed?"
A. "I did."
Q. "Did you get any results?"
A. "I got pretty good results."
Q. "If you continued to take it tell what happened to your condition, whether you got better or worse."
A. "It did wonders for me—felt better than I have in years."
Q. "Do you feel worse or better?"
A. "Wonderful—It did not come back, not even in the spine."
Q. "It did not come back at all?"
A. "No."
Q. "You are free from pain today?"
A. "Yes."
Q. "Did you take any other medicines at that time?"
A. "No."

Mrs. Alice Guardia:

Q. "Will you tell the Court what you were suffering from at that time?"
A. "Pain in my right shoulder—could hardly move my arm. I went to Dr. Snelling for it"
Q. "What did he diagnose it as?"
A. "Arthritis."
Q. "This medicine, did you take it according to directions?"
A. "Near as possible I did."
Q. "Mrs. Guardia, what results, if any, did you get with reference to your pain . . .?"
A. "It left me."

Mrs. F. M. Tatum:

Q. "—did you have occasion to consult Dr. Snelling on account of some ailment you had in your joints?"
A. "Yes, I did."
Q. "At that time you were suffering in what part of your body?"
A. "My knee was paining me some."
Q. "Did Dr. Snelling give you any medicine for this?"
A. "Gave me this—(Reached for Tri-Wonda treatment which is exhibit in evidence)."
Q. "Did you take according to the prescription?"
A. "Yes."
Q. "What results, if any, did you get from it?"
A. "Helped me quite a bit—taken some time—maybe six weeks—don't know how long—after a while the pain ceased—quit taking it."
Q. "You definitely got your pain relieved as a result of it?"
A. "Yes, I did."

if, as indicated in a general way in the majority opinion, some inconsistencies developed or contradictions arose, the trial court had the duty of considering all of the testimony and arriving at the conclusion which to it was most consonant with the truth.

Mr. C. E. Cuevas:

Q. "Mr. Cuevas, at the time you came to see Dr. Snelling will you tell the Court how you were suffering?"
A. "All in my joints and my knuckles, knees and the back of my shoulder."
Q. "Did Dr. Snelling give you any medicine to try?
A. "That is right."
Q. "Did you take it the way the doctor told you to take it?"
A. "That is right."
Q. "Were you feeling any better when you returned to him?"
A. "That's right."
Q. "What was your condition, Mr. Cuevas, had it improved right along or not?"
A. "That is right. I was working and feeling better."
Q. "Are you free of pain in your joints now?"
A. "Yes, sir."

Mrs. W. E. Lizana:

Q. "Who is your regular physician at this time?"
A. "Dr. Snelling."
Q. "Where were you suffering?"
A. "In my arms and hands."
Q. "Were they giving you much pain or not?"
A. "Right smart, yes, sir."
Q. "What kind of medicine did Dr. Snelling ask you to try?"
A. "This Tri-Wonda."
Q. "Now, Mrs. Lizana, did you follow the doctor's directions and take the medicine?"
A. "Yes, I did."
Q. "Then tell the court whether it helped you or not?"
A. "It certainly did help me, as far as I know. My fingers couldn't bend. I couldn't do much, and I think it did me a lot of good."
Q. "Did it get you to where you could bend your fingers or not?"
A. "Yes."
Q. "Do you feel you did get very definite relief from the medicine?"
A. "I certainly did."
Q. "Did it relieve you from your pain?"
A. "Certainly did."

Walter V. Cross:

Q. "Will you tell the Court what caused the condition that you are in at the present time—what you have been suffering from?"
A. "Diabetes and rheumatoid arthritis."
Q. "At the time you took Tri-Wonda for the first time how were you suffering at that time with reference to pain in your joints or body?"
A. "Yes, I had a lot of pain in my arms, neck and back and some in my legs."
Q. "At this date are you in comparative comfort comparative to conditions before taking Tri-Wonda?"
A. "Oh, yes, definitely."

Mrs. Cennie Bell Anderson:

Q. ". . . how were you suffering, Mrs. Anderson? What parts of your body were involved in this pain?"
A. "It started in my left limb, foot, knee and in both thumbs."
Q. "Were the joints swollen or not?"
A. "They were swollen."
Q. "Before you began taking the Tri-Wonda, Mrs. Anderson, will you tell the Court whether or not the swelling and pain you had had affected your walking or not?"
A. "Indeed it had. I hurt getting up in the morning and would have to hold on to things and just slide my feet along."
Q. "After you had been taking Tri-Wonda for at least three weeks you began to walk better or not?"
A. "I would walk better and kept on improving. I do all my work now."

Mr. Edwin W. Whitehead:

Q. "At the time you consulted Dr. Atwood what was your condition? How were you suffering? What caused you to suffer?"
A. "I was hurting. The Doctor said it was arthritis. It was in my hips, back, legs from the knees on down—bad."
Q. "Swollen or not?"
A. "Some."
Q. "Referring to the pain, were you suffering much pain or not?"
A. "Yes, sir."
Q. ". . . you had been taking the Tri-Wonda treatment as the Doctor gave it to you and as prescribed on the bottle, taking it like it said on the bottle?"
A. "Yes."
Q. "At that time how did you feel . . ."
A. "I began to feel better."

"I think, too, that the majority is a little hard on appellee's experts, led doubtless by the passage quoted in the majority opinion from Professor Wigmore's work on Evidence. The majority well denominates what it quotes as 'Wigmore's comment.' The quotation shows that it is the author's personal opinion, and an examination of the cases cited will show both that none of them support the comment and that no case from any Federal court or any Mississippi court is cited in support of it.

"The Mississippi rule, which is the one applicable here, Rule 43(a) F.R.C.P.,[7] is thus stated in the first syllabus of *King* v. *King, et al*, S. Ct. Miss. 1931, 134 So. 827:

> To testify as an expert, witness need not be infallible or possess highest degree of skill; to testify as 'expert,' it is generally sufficient that witness possesses peculiar knowledge respecting matter involved not likely to be possessed by ordinary layman.[8]

"These holdings by the Supreme Court of Mississippi seem to be in line with the general rule as announced by American Jurisprudence, Vol. 20, Evidence, § 785, p. 659, where it is held that one may be competent to testify as an expert although he is not shown to be highly qualified to speak upon the subject, and that: 'It is usually held that any person whose profession or vocation deals with the subject in hand is entitled to be heard as an expert, leaving the value of his evidence to be tested by cross-examination and determined by the jury.'

"It is my opinion also that the majority is too strict in its attitude towards testimony of lay witnesses. All that is left in this case deals with the treatment of symptoms. The lay witnesses knew their own symptoms and they knew what happened to those symptoms when the accused drugs were administered. Those symptoms were admitted by all of the witnesses for the Government and the appellee to be symptoms of rheumatism, arthritis, etc. Under the general and the Mississippi law, the lay testimony admitted by the court below was competent.[9]

Q. "During all that time you continued to take this medicine?"
A. "Yes."
Q. "Tell the Court whether you continued to improve or not."
A. "Oh, yes, yes sir."
Q. "With reference to the swelling, what occurred in the joints that were affected, did it go down or not?"
A. "It went down."

The foregoing testimony is typical of that given by the twenty-two lay witnesses testifying for the defendant.

[7] "New York Life Insurance Co. v. Schletter et al., 5 Cir., 1953, 203 F. 2d 184; White et al. v. Holderby et al., 5 Cir., 1951, 192 F. 2d 722; and Petroleum Carrier Corp. v. Snyder, 5 Cir., 1947, 161 F. 2d 323.

[8] "See also Floyd v. State, S. Ct. Miss. 1933, 148 So. 226, 231, where the Supreme Court reversed the judgment of a trial court in part because the court below refused to let a doctor give his professional opinion that a second blow could not have been self-inflicted by a person who had already been struck one blow. The Supreme Court stated: 'It is true that Dr. Crisler may have had more experience as a surgeon, or higher training as a student, but Dr. Sigrest had been trained as a general practitioner and had had 30 years' experience. . . . [We think] that a physician who had made the study of the human body a profession, and who had considerable practice, could be called an expert.'

"And in J. W. Sanders Cotton Mill v. Moody, S. Ct. Miss., 1940, 195 So. 683, 689, the court held that a chiropodist could testify as an expert in the interpretation of X-ray pictures and respecting injuries to the foot generally even though he had not had the training ordinarily required of a physician.

"And in Wallace v. State, 1948, 35 So. 2d 703, 704, the Supreme Court of Mississippi quoted 20 Am. Jur. page 692 in its statement that: 'Any person who has, by sufficient experience, acquired adequate knowledge of X-rays and their interpretation may qualify as a witness.' The court repeated also that 'It is sufficient if he possesses peculiar knowledge, wisdom, or information regarding the subject matter, acquired by study, investigation, observation, experience, or practice, not possessed by the ordinary layman or inexperienced person.'"

[9] The Supreme Court of Mississippi in Pearl River Valley R. Co. v. Moody, 1937, 171 So. 769, sanctioned the receipt of testimony given by a lay witness, in an action to recover for injuries sustained, as to his continuous pain and suffering. Also, in Illinois Cent. R. Co. et al. v. William, 1926, 110 So. 511, it was held by the Mississippi Supreme Court that an instruction to the jury was correct which permitted the consideration of testimony given concerning the physical pain and suffering endured by a party, holding that such testimony was competent.

This law as stated by the courts of Mississippi also appears to be in accord with the general law, as it is given in 32 C.J.S., Evidence, § 513, p. 171: "While a nonexpert or

"What the majority really holds here is that the trial court drew the wrong conclusions from the competent testimony. I cannot agree with that holding. I think there was ample evidence to support the trial court's findings and conclusions as to the facts.

"Surely this case is not ruled by *United States* v. *Hoxsey Cancer Clinic, et al.*, 5 Cir., 1952, 198 F. 2d 273. We held that the literature used in *Hoxsey* represented that the drugs involved would cure some internal cancers and relieve other internal cancers.[10] In the case before us the trial court specifically enjoined, as will appear from the quotation in Note 3 *supra*, the use of any written or printed matter 'which represents or suggests, directly or indirectly, that the drugs, or either of them, or any similar drug, is a cure or adequate treatment for any form of arthritis or rheumatism. . . .' Appellee did not appeal from that portion of the judgment, claiming that she had made no such representations. The case before us involves, not any representations concerning cures, but representations relating alone to relief from some of the symptoms or 'miseries' attendant upon the maladies under consideration.

"While it is my opinion that the merits should not be reached and that the case ought, on the motion to dismiss the appeal, to be sent back to the trial court for further handling, I think that the majority opinion fails to demonstrate that the findings and conclusions of the trial court are clearly erroneous.

III.

"Finally, I think it is unwise, in a case such as this, to substitute our judgment for that of the district judge in refusing or granting injunctive relief in connection with the enforcement of statutes such as that before us. The formulae here involved had been originated about 1900 by Reverend H. A. Hall who seems to have marketed them successfully until about 1938 when he stipulated with the United States Post Office Department to discontinue using the mail in connection with them, confining his marketing thereafter to the State of Florida. The appellee's connection with them began in 1950 when, being a sufferer from rheumatoid arthritis, she first took the Hall products and attributed her improvement to them. The development of the sale of the products under the name of 'Tri-Wonda' followed that experience.

"Officials of the Government began investigating the appellee in 1951 and various dealings, most of them controversial, have been had between them from that date until the filing and disposition of this civil action.

"The trial court lived with the whole controversy intimately for a period of about four years, and the conclusions reached by him were based upon a 'feel' of the case we could not possibly acquire. I do not think we should disturb a finding and judgment entered by such an able, conscientious and experienced trial judge as the one who sat on this case without a clear showing of abuse of discretion.

"That has been the policy of this Court for many years, *Walling* v. *Florida Hardware Co.*, 1944, 142 F. 2d 444; *Mitchell* v. *Hodges Contracting Co., et al.*,

---

lay witness may not give expert testimony as to his physical condition, he may state simple inferences drawn from his conscious subjective sensations concerning such condition:" and in 20 Am. Jur., Evidence, § 859, p. 720; "One, not an expert, may testify as to the state of his own health."

[10] The following quotation, made up of several disconnected statements in the long opinion, demonstrates that this Court construed the representations there condemned as assuring those reading it that the drugs would cure internal cancer:

[Page 276] "For the purpose of this decision and in determining the truth of such representations, we will accept the more restricted position, to which the Government is driven, that the precise extent of successful cures is immaterial since, it is contended, that the representation that any cure can be effected by use of the medicine is false and misleading. . . . It is difficult to imagine that one thinking himself inflicted with the dire disease of cancer and reading and considering the references to these listed patients, and the testimony there set forth, . . . would reach any other conclusion than that the persons listed were cured of cancer by the Hoxsey drugs.

[Page 280] ". . . Our consideration of the record and the nature of the issues involved has led to the firm conclusion that the trial Court's findings of fact that the representations in the labeling were neither false nor misleading, and that the brownish-black and pink-colored medicines were efficacious in the cure of cancer in man are clearly erroneous. . . .

[Page 281] "Furthermore, as we have held, the overwhelming weight of the credible evidence requires a conclusion that the representation that the Hoxsey liquid medicines are efficacious in the cure of cancer is likewise false and misleading."

1956, 238 F. 2d 380, 381; *Mitchell* v. *Bland*, 1957, 241 F. 2d 808, 811; *Mitchell* v. *Strickland Transportation Co.*, 267 F. 2d 821; and our decisions have been based upon Supreme Court decisions.[11]

"In *Mitchell* v. *Lublin McGaughy and Asso.*, 1959, 358 U.S. 207, 215, the Supreme Court referred to our decision in *Bland supra* at page 810, from which we quote:

> But we do not consider these considerations of controlling importance. Even assuming appellant's contentions to be sound in both instances, the Court would have been justified in either granting or denying injunctive relief under the broad discretion lodged in it by accepted equitable principles. . . .
>
> The trial Court evidently reached the conclusion that more could be accomplished towards enforcement of the law and towards bringing appellant into cooperative conformity with its provisions by withholding the drastic remedy of injunction than by using it. . . .
>
> The problem before the Court below did not involve litigation between two private individuals only; it related primarily to the business of the public and the public interest was entitled to primary consideration. . . .
>
> The same ideas were expressed by the Supreme Court in dealing with the enforcement of the Emergency Price Control Act, . . . in a case wherein the problem presented was quite similar to that before the Court in this case. Hecht involved a prayer for injunctive relief where a spot check of seven out of more than one hundred departments of a large store revealed four thousand five hundred violations of the law. After a full hearing, the District Judge denied injunction pursuant to its general equity powers: "In a case such as this an injunction should not issue unless thereby better compliance with law may be enforced . . . and in my judgment an injunction would not be in the public interest . . ." The Court of Appeals for the District of Columbia reversed on the theory that the District Judge had given too wide a sweep to traditional equity powers. The Supreme Court granted certiorari and reversed the action of the Court of Appeals approving what the District Court had done . . .

"I think the case before us presents a much stronger appeal for approving the district judge's use of his discretion than any of those mentioned.

"I think that the recognition by appellate courts that discretion belongs uniquely to the district courts is of very great importance and, for that reason, I have felt constrained to set down at some length the grounds of my dissent in this case."

On 2–13–61, the United States District Court for the Southern District of Mississippi entered a decree of permanent injunction enjoining the defendant from:

(a) Directly or indirectly introducing or causing to be introduced into interstate commerce, an article of drug, known as "Tri-Wonda," "*Tri-Wonda Treatment*," "Tri-Wonda No. 1," "Tri-Wonda No. 2," or "Tri-Wonda No. 3," or any similar drug, the labeling of which, within the meaning of 502(a) of the Act is false or misleading in any particular, and more specifically any such drug which is accompanied by the leaflets entitled "You May Now Profit by the Experience of Others," "Attention Arthritics," the letters entitled "Special Bulletin," "Dear Friend," "Thank you for your letter of recent date," "I am glad to tell you about my experience," and testimonial letters from users of "Tri-Wonda," or any other written, printed, or graphic matter, which represents or suggests, directly or indirectly, that the drugs, or either of them, or any similar drug, is a cure, or an adequate treatment, or is useful for treating any form of arthritis or rheumatism, or that they are beneficial, or give

[11] Such as Texas v. Pullman Co., 1941, 312 U.S. 491; and Hecht Co. v. Bowles, 1944, 321 U.S. 321.

relief, or have any value for all forms of arthritis and rheumatism, or that they are beneficial, effective, or have any value in the cure, mitigation, relief, or treatment of muscular aches, pains, soreness, stiffness, and swellings or any other symptoms which may accompany any form of arthritis or related diseases;

(b) Directly or indirectly doing or causing to be done any act with respect to any such drug, while held for sale after shipment in interstate commerce, which results in the drug being misbranded within the meaning of 502(a) of the Act, specifically including, but not limited to the following acts while the drug is held for sale after shipment in interstate commerce:

1. The use in the sale of the drug of any of the above written, printed or graphic matter, or of any other written, printed, or graphic matter containing any of the above claims or representations;
2. Representing in any manner, that the drug is useful in the prevention, treatment, mitigation, or cure of any disease, condition, or symptom, that is not stated and/or enumerated in the labeling of the drug together with precise directions for effective and safe use in each such disease, symptom or condition; and

(c) Directly or indirectly introducing or causing to be introduced into interstate commerce, any such drug with labeling that does not include a statement and enumeration of all diseases, conditions, and symptoms, for which the article is intended to be used together with precise directions for effective and safe use in each such disease, condition, or symptom.

The decree of injunction further ordered that defendant should give notice of the provisions of this decree to certain of her associates; that the effective date of the injunction should be 3–13–61; that the defendant's application for a further stay pending appeal was denied; and that all costs of court were taxed against the defendant.

Subsequently, on 3–23–61, the United States District Court for the Southern District of Mississippi overruled the defendant's motion for a new trial and, on 3–25–61, the court overruled the defendant's motion for a stay of the final injunction. The defendant appealed the latter ruling, and the United States Court of Appeals for the Fifth Circuit dismissed this appeal. On 10–10–61, the defendant's motion to retax costs was granted in part in that the defendant was excepted from payment of the costs of multilithing the transcript of the record of the trial.

6552. Various drugs. (Inj. No. 400.)

COMPLAINT FOR INJUNCTION FILED: On 3–20–61, S. Dist. Calif., against Hamid Bey, t/a Bey Vita Products Co. and Coptic Fellowship of America, Los Angeles, Calif.

NATURE OF BUSINESS: The defendant was engaged in the business of promoting, through lectures and through the dissemination of letters, and other written, printed, and graphic matter, the interstate sale of the following articles: *Bey Saffto* composed of unsaturated fatty acids derived from safflower oil, and vitamin B_6; *Bey VA* composed of vitamin A–from lemon grass oil; *Bey Natural VC* composed of vitamin C–from rose hips with rutin; *Bey VE* composed of alpha-tocopherol; *Ro-Qee-Jel capsules* composed of royal jelly, vitamin B_1, vitamin B_{12}; *Bey Vita Natur-Cal* composed of calcium, phosphorus, and vitamin D; *Bey Vita RG Soya Lecithin* composed of oil-free lecithin derived from soya bean oil; *Bey Vita yeast tablets* composed of yeast containing vitamins B_1 and B_2; *Bey Proto-X* composed of amino acids with vitamins B_{12}

and B_1; and *Calpans* composed of brewer's yeast, calcium pantothenate, and vitamin B_1.

CHARGE: The complaint alleged that the defendant caused the above-named articles to be shipped to various cities throughout the country where he gave lectures on health subjects and made therapeutic claims for the articles; that on the basis of such claims, the audience was induced to purchase the articles which were available for sale at the lectures; and that the defendant also caused the above articles to become misbranded under 502(f)(1), when shipped and while held for sale, because the labeling of such articles failed to bear adequate directions for use since it did not declare the conditions and purposes for which the defendant orally represented and suggested that the articles were effective, namely: *Bey Saffto* for change of life, overweight, dry skin conditions, itchy skin, skin breaks, to oil skin, to feed glands, to remove wrinkles, to dissolve fat, and to remove body impurities; *Bey VA* for bad eyesight, eye sensitivity, cataracts, glaucoma, poor blood, arthritis, liver ailments, to neutralize excessive mucous in membranes, and to purify blood stream; *Bey Natural VC* for infected blood stream, kidney infection, high blood pressure, capillary fragility, impaired circulation, bleeding, stomach ulcers, varicose veins, mucous in sinus, ears, and membranes, anemia, arthritis, to coagulate blood in skin cuts, and to eliminate mucous from membranes; *Bey VE* for cataracts, glaucoma, heart trouble, muscular degeneration, skin breaks, arthritis, to renew muscle tone, and to sober up from drunkenness; *Ro-Qee-Jel capsules* for cataracts, glaucoma, heart trouble, muscular degeneration, skin breaks, arthritis, to renew muscle tone, to sober up from drunkenness, and liver conditions; *Bey Vita Natur-Cal* for brittle nails, brittle hair, varicose veins, arthritis, change of life in women, to quiet and relax, to induce sleep, and to build blood; *Bey Vita RG Soya Lecithin* for inflammation of lining of veins, brittle veins, brittle capillaries, brittle blood vessels, impaired circulation, sluggish blood, anemia, abnormal heart and blood pressure, obesity, liver trouble, kidney trouble, blood trouble, to dissolve cholesterol in blood, blood stream, and liver, and to provide food for brain and nerves; *Bey Vita yeast tablets* for poor digestion, obesity, duodenal ulcers, intestinal ulcers, impaired nerves, and impaired muscles; *Bey Proto-X* for diabetes, stomach ulcers, and arthritis; and *Calpans* for liver conditions, to promote growth in children, and to restore original color to hair.

The complaint alleged also that, should the articles bear labeling stating such conditions and purposes, the articles would then be misbranded within the meaning of 502(a) since such labeling would be false and misleading in that the articles would not be effective for such conditions and purposes.

DISPOSITION: On 3–27–61, the defendant having consented, the court entered a decree of permanent injunction enjoining the defendant against commission of the acts complained of.

6553. Tri-Sulfa tablets. (F.D.C. No. 45511. S. No. 61–029 R.)

QUANTITY: 38 btls. at St. Joseph, Mo., in possession of United Pharmacal Co., Inc.

SHIPPED: 12–27–60, from New Rochelle, N.Y.

LABEL IN PART: (Btl.) "100 Tablets UPCO Tri-Sulfa Tablets Formulated for United Pharmacal Co. * * * Each tablet contains: Sulfadiazine 2½ grains Sulfamerazine 2½ grains Sulfathiazole 2½ grains Usual Dose * * * Warning * * * Caution."